Data Sharing and Intellectual Capital Working Group – Regulatory Team
Teleconference
November 15th, 2004, 2:00 P.M. EDT

MEETING MINUTES
Attendees:
Howard Bilofsky
Amin Chisti
Mark Watson
Elaine Brock
Tom Cassavant
Don Connelly
Ed Quick
Mike Becich
Bob Robbins
May Jo Deering
Wendy Patterson
Phan Winter

A. Review of minutes for the meeting on November 1st.
Howard called meeting to order. Minutes approved

B. Update on SPWG face-to-face meeting (Strategic Planning Working Group)
   ▪ Key decisions affecting DSIC WG
Mark Watson and Howard attended. Howard wishes minutes were available because its difficult to summarize all that happened. Tom Casavant will try to abstract DSIC issues from minutes. Mike Becich indicated there was a discussion of who are the developers and adopters. He will also summarize meaty issues relevant to DSIC. There was a common lament about how many caBIG meetings there were and the difficulty organizing lives around this issue. There was a concern that way too many subcommittees and special interest groups have been formed. We should focus on the 29 already identified development projects and focus on developer and adopter sites that have been funded. There was a bias to action. We're a community of communities so there is pressure to keep pathways to involvement open.

Another theme was a discussion about sharing information and publishing minutes of all the meetings and making it easy to find, painless and open. The publication policy document doesn't seem consistent with that. Ken Beutow would like to avoid many layers of review, for instance. See Item D below for more feedback.

C. Continue discussion of proposed team plan – Strawman
Howard reminded us of the bias to action and so he'd like to get a list of regulatory expertise accessible to the task group, both local ones and national ones. Local experts may be helpful to engage because they may be responsible for approving local activities. It was thought the strawman might be strengthened first in terms of inclusiveness of issues before identifying experts.

D. Feedback on proposed publication policy
Following the criticism regarding the publication document stated during the Strategic Planning Work Group, some Regulatory task members voiced their concerns about the document. What is considered a caBIG publication? Does it include summary of minutes, white papers, journal submissions or only journal submission. Was the publication document really intended to focus only on published papers? What's the purpose of the review? Perhaps a certification process would be preferable. Mike Becich, who helped author the document, described some of the rationale that was behind it. There are many reasons for a review and approval process in a situation involving collaborative research. For instance, we want to monitor whether output from the caBIG project is beginning to flow. More importantly, publications that describe science should let program people and others provide input into the publication process. While this might mean a two-week delay in the

publication process, this leads to improvement in scientific content. In collaborative efforts, science is a broader effort, and facilitating that collaboration by manuscript review can lead to synergies that strengthen the science and broaden the impact of a paper. If there are four individuals on a review committee, not all would have to rule on abstracts to speed turnaround. Howard decided this concern should be referred to entire DSIC. Phan asked that written comments and criticisms be provided to her, and she'll combine and share them with DSIC WG members.

E. Use cases / scenarios solicitation
- Comments on template

Phan has gotten no emailed comments yet. She recommended working on these items off line between meetings and encouraged written comments for Bob's draft and the templates. Brian Gilman from the Proprietary group said he'd send a model scenario, a real use case obtained using this template, which might be more helpful in conveying what a use case should look like. Phan will circulate a scenario based on this template. He was concerned that the model circulated was too close to what a developer would want and too far from where a needs definition would actually begin.
- Adopter/developer pairings

In order to speed progress in defining use case, it had been proposed that we focus on funded adopter/developer pairings. A list identifying such pairing was obtained from the ICR workspace and circulated. Similar pairings for the CTMS and Tissue Banking workspaces are not yet available. It was urged that we identify those pairs because of issues of privacy and patient safety that they will generate. Some task group members have been assembling some examples of regulatory-oriented use cases.

F. Draft position paper "Recommendations for Security Administration and Access Control" by Bob Robbins

Howard Bilofsky presented the proposed position paper on Security Administration and Access Control during the SPWG fact-to-face meeting. They agreed this was a true strategic issue.   The need to maximize flexibility to accommodate changes seemed to be accepted by the Strategic Planning Working Group. There was a concern that perhaps it should be reviewed at a higher level to ensure it has caBIG-wide input and agreement. There's both a need for education as well as deliberation so that all really understand the key issues and how it meshes with their local culture.

It was suggested that we take the conclusions in Bob's paper and turn them into recommendations. Wendy thought the next step should be to circulate the edited document to the DSIC WG as a whole and discuss it and the publication policy together, then send both documents to the Strategic Planning Working Group. Phan and Bob called for members to get their comments in promptly so the documents could be sent back to the SPWG.

G. Next meeting

Phan asked whether the Regulatory Team wants to meet before December 9th, which is scheduled for the entire DSIC WG group meeting. The general consensus was no and that significant work could be done off line. All team members are asked to:
1) Look at Bob's paper and comment – it's urgent to get this feedback soon so we can get something finalized for the strategic planning committee. If there's a strong reservation, get it back before December 9th.
2) Critique publications policy and provide comments to Phan.
3) Keep December 13th and 20th in mind as dates for the next Regulatory Team meeting. The Strawman document will be strengthened and further discussed at this next meeting.

A question was brought up about the coordination at a federal level of related funding opportunities. A case in point is RFA-RM-04-022, National Centers for Biomedical Computing. The investigators who are applying are from entirely different groups in most of caBIG participating organizations. Wendy agreed to look into this.